HyperCare: a Prototype of an Active Database for Compliance with Essential Hypertension Therapy Guidelines

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HyperCare is a prototype of a decision support system for essential hypertension care management. The medical knowledge implemented in HyperCare derives from the guidelines for the management of mild hypertension of the World Health Organization/International Society of Hypertension,[1] and from the recommendations of the United States Joint National Committee on Detection, Evaluation and Treatment of High Blood Pressure.[2] HyperCare has been implemented using Chimera,[3] an active database language developed at the Politecnico di Milano. HyperCare proves the possibility to use active database systems in developing a medical data-intensive application where inferential elaboration of moderate complexity is required.

INTRODUCTION

An increasing number of institutions are approaching the problem of distributing and improving the use of guidelines in patient care. Electronic medical record systems have the potential of making a great impact in the increased utilization of guidelines since these systems are often used by clinicians at the time when care is delivered.[4] In some cases guidelines are put into the systems in narrative form; in others, several independent logic modules react when actions prescribed by guidelines do not take place.[5]

Systems integrating both data-maintenance and decision support functions have requirements that span from efficient data-manipulation, typical of databases,[6] to inferential elaboration, typical of expert systems.[7] Active databases[8] may be considered as a bridge between these two kinds of systems: they have both the efficiency of databases in handling data storage and retrieval and the power of a complete rule language in expressing complex inference mechanisms. Moreover, in active databases the knowledge is collected in schema and rules enforced by the database manager. The same knowledge is thus available and transparent to all applications accessing the database. This property, known as *knowledge independence*, allows knowledge to be easily maintainable.[8]

The inferential complexity of the guidelines for the management of hypertension and the necessity of archiving the huge amount of data acquired in periodic follow-up visits make active databases particularly interesting when developing decision support systems for hypertension guideline compliance.

HyperCare is a prototype of a decision support system for compliance with essential hypertension management guidelines,[1,2] implemented using the active database language Chimera.[3] The choice of this language is justified by the rich object-oriented data definition language and the expressive syntax for active rule definition offered by Chimera.

Even if the system that we propose is not the first support system for hypertension management,[9,10] as far as we know this is the first application of active databases to medical guideline compliance.

BACKGROUND

Essential hypertension treatment

Despite advances in medical knowledge about hypertension, essential hypertension, which consists of abnormally high blood pressure from unidentified pathological causes, remains a complex and widespread disorder.[11] Patients with hypertension, even those with mild elevation of blood pressure, are at increased risk of cardiovascular disease, whether or not symptoms are present.[1] For this reason, it is extremely important, both for the individual and the society, to reduce abnormally high blood pressure whenever possible.

The first phase of the diagnostic procedure for essential hypertension consists in assessing the importance of the disorder. According to the guidelines, several blood pressure measurements have to be performed on different conditions. Besides, medical tests are executed to check damages to organs that are generally harmed by hypertension (target organs). On the base of acquired clinical data, a pharmacological or non-pharmacological treatment may be chosen. The pharmacological therapy is usually long-lasting (generally life-long) and requires periodic follow-up visits.

HyperCare is based on the guidelines for the management of mild hypertension of the World

Health Organization/International Society of Hypertension,[1] and on the recommendations of the United States Joint National Committee on Detection, Evaluation and Treatment of High Blood Pressure.[2]

Chimera active database language

Chimera integrates an object-oriented data model, a declarative query language and an active rule language for reactive processing. It provides all the characteristics commonly ascribed to object-oriented data models. Moreover, multiple inheritance and multiple class instantiation are supported. Chimera active rules have both the semantic power of expert systems rules and the typical data-handling efficiency of databases. A complete definition of Chimera can be found in reference.[3]

HYPERCARE DESIGN

The development of HyperCare involved an extensive knowledge-acquisition phase, concerning the study and the analysis of the guidelines. During meetings and discussions with medical experts from the *International Heart School* of Bergamo (Italy), application requirements have been clearly defined. The guidelines have been analyzed and discussed with respect to their implementation in an active database context. The schema of the database and the main functions of the system have been designed and implemented according to direct supervision of medical experts. The expressiveness, usability and power of the used language allowed the medical experts to collaborate in the development of the code of HyperCare suggesting amendments and improvements.

Two features are mostly relevant in HyperCare architecture: its object-oriented schema and its reactive computational paradigm implemented through active rules.

Object-oriented schema definition

The object-oriented schema of HyperCare represents entities involved in hypertension treatment through object classes (e.g., *physician*, *patient*, *drug*, *test*, *visit*). In Figure 1 is shown part of the schema; square boxes represent classes, while arrows represent inheritance relationships (the class from which the arrow originates inherits from the class to which the arrow points).

Inheritance avoids code redundancy. As an example, attributes common to all possible different patient populations (e.g., identification code, weight) are defined in the class *patient*. Classes of patients affected by specific diseases (e.g., *ehtPatient* class for essential hypertension patients or *dmPatient* class for diabetic patients) inherit all the attributes of the class *patient* and define only some further attributes peculiar to them.

In Chimera an object may simultaneously belong to a number of classes even if not related in the inheritance hierarchy. This feature has been used to represent the complexity of the health condition of a patient, that can be affected by more than one disease. Hence, an object referring to a patient belongs to all the classes representing his/her diseases: e.g., the object related to a diabetic and essential-hypertension patient is simultaneously an instance of the classes *ehtPatient* and *dmPatient*. To test if a patient is affected by some peculiar disease, a simple class-membership test is required.

HyperCare has been developed thinking to it as a module of a complete computer assisted data management system. Therefore, the schema of the database reflects the assumption that many of the data used or updated by HyperCare may be shared with other applications. HyperCare could be a part of a full-fledged health care management system composed of similar modules devoted to the management of other kinds of diseases and all sharing the same database of patients. Furthermore, it may be integrated with management applications to share administrative data.

The inheritance tree of HyperCare schema is open to future extensions, i.e., classes referring to diseases not previously considered may be added to the schema without modifying its organization. This makes HyperCare adaptable to evolving operative conditions and medical knowledge.

Active rules

The code of Chimera active rules is divided in three parts:[3,8]

- the *event part*, which specifies one or more events (creation, deletion or modification of objects) that can trigger the rule (i.e., trigger the interpretation of its condition part);
- the *condition part*, which specifies a precondition

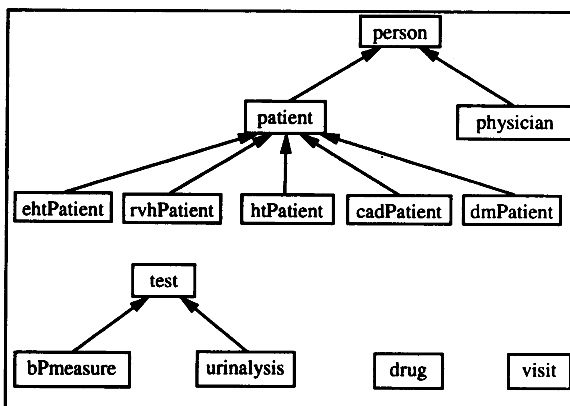

Figure 1 - The class schema

on the database state for the action part to be executed;

- the *action part*, which contains one or more operations (queries or updates) that will be executed on the database if the rule has been triggered and its condition part has been satisfied.

An example of a rule that verifies an integrity constraint on the maximum dosage of a drug is:

```
define trigger checkMaxDosage
    events
        modify(drug.dosage)
    condition
        drug(Drug),
        holds(modify(drug.dosage),Drug),
        Drug.dosage > Drug.maxDosage
    actions
        modify(drug.dosage, Drug, Drug.maxDosage)
end;
```

In this case, the event part specifies that the rule will react upon a modification of the attribute *dosage* in objects of the class *drug*. The condition part makes a binding between the object variable *Drug*, of the class *drug*, and the objects that have been modified; then it checks if the new dosages are higher than the allowed thresholds. In this case, the action part is executed. Its purpose is to suggest the physician to decrease the dosages at the highest allowed level.

One of the most interesting features of HyperCare is its reactive computation capability typical of active databases. HyperCare works as if it were a background program waking up as soon as relevant data are inserted. The state of the diagnosis and therapy of a patient evolves in parallel with the evolution of his/her blood pressure measurement and medical tests. Whenever the state of the database is modified, the system reacts according to the knowledge implemented in its active rules, i.e.:

- When new blood pressure data are inserted, the suggestion to update the therapy (adding or deleting drugs or modifying dosages according to the measured pressure trend) is automatically given.
- When a new drug is prescribed to the patient, contra-indications and side effects connected to hypertension are verified (and if found, it is suggested to the physician to suspend the new drug).
- When data from accomplished visits are inserted, new visits are automatically booked.

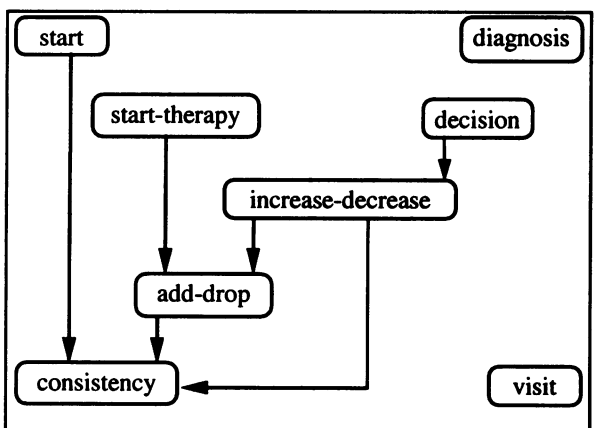

Figure 2 - The strata of active rules

To assure an organic development of HyperCare, active rules have been divided in 8 strata (see Figure 2): *start*, *diagnosis*, *start-therapy*, *decision*, *increase-decrease*, *add-drop*, *consistency*, *visit*. In Figure 2, rounded boxes represent strata, while arrows represent trigger-activation relationships (the rules of the stratum from which the arrow originates contains actions which can trigger at least one rule of the stratum to which the arrow points). This stratification divides the system in modules containing functionally related rules, thus improving readability and maintainability of code and allowing a formal demonstration of termination according to the *event-based stratification* model.[12,13]

In the following subsections we give a brief description of each single stratum of rules.

Start stratum. The rules of this stratum react to an abnormally high blood pressure value inserting the patient object referring to it in the class of essential hypertension patients (*ehtPatient*). The insertion is performed only if the considered patient is not affected by diseases causing secondary hypertension. All the visits required to assess the importance of hypertension are automatically booked.

Diagnosis stratum. The rules of this stratum end the diagnostic phase deciding, after as few as possible diagnostic visits, whether the patient is really affected by essential hypertension. When the diagnosis completes, these rules delete the remaining booked diagnostic visits, and, in case of positive diagnosis, they book all the tests required to assess damages to target organs or diseases for which hypertension is considered a risk factor.

Start-therapy stratum. The rules of this stratum decide if and when a pharmacological treatment should be administered to a patient. The decision is based on various parameters among which: blood pressure, other diseases, time span of the non-pharmacological treatment. The choice of the actual drug to administer is not implemented by the rules of this stratum, but by the rules of the add-drop stratum. Simply, the rules of this stratum trigger the rules of the add-drop stratum. This decoupling between the decision to modify and the actual modification of the therapy allows free combination among rules that decide therapy changes and rules that implement the changes according to the final decision of the physician and the patient's peculiar characteristics. This mechanism grants flexibility and expressiveness without redundancy of rules.

Decision stratum. The rules of this stratum decide if and when to suggest to increase or decrease the dosages of drugs. The decision is based on the difference between actual and target systolic and diastolic pressure values. However, if the current therapy has not been tested for at least two weeks, HyperCare waits before suggesting any therapy change. As for the previous stratum, the rules of the decision stratum do not directly implement the modification of dosages; they just trigger the rules of the increase-decrease stratum that will actually modify drug dosages.

Increase-decrease stratum. This stratum contains a specific rule to increase or decrease the dosage of any single kind of drug. According to patient's status the system decides which rule has to be applied. If the dosages of all the drugs prescribed to a patient cannot be increased or decreased since they are already the highest or the lowest possible, appropriate rules of this stratum switch the request to increase or decrease dosages to a request for adding or dropping a drug. This request will be dispatched by the rules of the following stratum.

Add-drop stratum. The rules of this stratum add or delete a drug to/from the patient's therapy. There is a specific rule for the addition or deletion of any single kind of drug.

Consistency stratum. The rules of this stratum verify the integrity constraints: range of dosages and consistency of pharmacological therapy (e.g., contra-indications among drugs).

Visit stratum. The rules of this stratum book visits for essential hypertension patients. The time interval among the visits is set according to the importance of the disorder and the type of treatment (pharmacological or non-pharmacological) of the patient.

IMPLEMENTATION FEATURES

The main decision support functions implemented in HyperCare are:

- management of recommended procedures for the diagnosis of essential hypertension;
- automatic booking of visits and medical tests;
- handling of pharmacological therapy, including indications and contraindications of drugs, target-organ damages, risk factors;
- filling of the patient medical record diary, including the recording of unexpected episodes.

Moreover, HyperCare lets the physician use his discretion whenever necessary. He/she can modify the target pressure values suggested by the system (therefore controlling the overall way HyperCare deals with a patient) or he/she can change the drugs and the dosages chosen by HyperCare. HyperCare will not interfere for at least two weeks with dosage change. Then, if the change has not been successful in reducing the patient's blood pressure to target values, HyperCare will suggest to the physician possible therapy modifications.

Many aspects of hypertension treatment depend on temporal events (e.g., the dosage of a drug can be increased only if it has been tested on the patient for a reasonable amount of time). HyperCare manages such temporal aspects checking the time when past events happened.

At the moment HyperCare is a prototype. Some functions that would be important for a complete full-featured system have not been implemented yet. The most relevant omissions are:

- HyperCare does not consider the history of patient's family in therapy decision, and it is not yet designed to manage the special requirements for hypertension treatment in children and pregnant women.
- HyperCare does not contemplate emergency treatment.
- The user interface is quite limited.

Additionally, HyperCare, according to the considered guidelines, does not deal with home or ambulatory blood pressure measurements since "no prospective studies are available providing prognostically valuable standards for home or ambulatory blood pressures".[1]

The prototype has been developed on Sun Workstations using the Algres testbed[14] for the Chimera language.

CONCLUSIONS

HyperCare is a prototype of a decision support system for essential hypertension care management according to international guidelines. In this prototyping phase of the system, no complete clinical validation of HyperCare has been carried out.

Nevertheless, the results of the described work are significant mainly for two reasons. First, they prove that an active database may be applied to encourage guideline compliance, supporting knowledge independence and a level of data-handling efficiency not easily achievable using traditional expert system shells. Second, they show that an expressive active database language as Chimera may be useful as a prototype language to formalize the functionality of a complex decision support system like HyperCare (see the *IDEA methodology* [3]). In particular, the high expressiveness and readability of the Chimera language allowed the consulted medical experts to read and understand the code of HyperCare. This gave them better understanding and greater confidence in the functions supported by the prototype. Knowledge acquisition is one of the main problems of the development of decision support systems. We have found that a readable prototyping language may speed up this phase allowing the experts to directly suggest the best way to represent knowledge.

The development of a complete product would require a considerable increase in the number of rules implemented in the central strata of the HyperCare prototype and the definition of a class for any disease that may possibly interfere with hypertension treatment. However, during the prototype development attention has been paid to implement at least an example, if not many, of all the possible types of rules and classes required in a full implementation.

Versions of HyperCare for low-cost and widespread computer systems are under consideration. A Chimera-SQL translator is currently under development.[3,15] It is our intention, as soon as this tool will be available, to translate HyperCare to Oracle SQL[16,17]. This will grant to the system the robustness of a commercial database and will allow us to extend the user interface, enhancing the interaction of the user with HyperCare. Finally, this Oracle version of HyperCare will be thoroughly validated in clinical environment.

Although current versions of Oracle SQL directly support active rules, Chimera was preferred to Oracle SQL for the prototyping of HyperCare because its code is much more readable by medical experts and easier to program.

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